

Exhibit D

In The Matter Of:

Rackliff vs. C.R. Bard

Suzanne Parisian, M.D.

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1 record.

2 **A My full name is Dr. Suzanne Parisian.**

3 Q And what is your present business address?

4 **A It's MD Assist, Inc., 7117 North 3rd Street,**
5 **Phoenix, Arizona.**

6 Q And you've been deposed before?

7 **A Yes, sir.**

8 Q Can you estimate for me how many depositions
9 you've given over the years?

10 **A Over -- since 1997, 180 depositions.**

11 Q So you are familiar with the process?

12 **A Yes, I hope. I think I am, but you never**
13 **know.**

14 Q I would just ask that if at any time I ask you
15 a question that you do not hear or do not understand,
16 please ask me to repeat it or rephrase it. And if at
17 any time you wish to take a break, please let us know
18 and we are happy to do so.

19 **A Yes, sir. Thank you.**

20 Q You said you've been deposed 180 times since
21 1997. Can you estimate how many times you've actually
22 testified in court?

23 **A I think I've been in court about -- I think**
24 **maybe about 50 times. I'm not sure.**

25 Q Can you estimate for me how many depositions

1 MR. LOPEZ: This is -- let me just say
2 this -- I know you are not supposed to -- but isn't
3 this outside the scope? We are talking -- she's here
4 for three cases, and now you are deposing her on the
5 MERIDIAN, and the MERIDIAN doesn't -- I mean, if you
6 want to make this about the MERIDIAN case, I guess we
7 can, but, I mean, I would just suggest to you that
8 these are Recovery cases.

9 MR. NORTH: This has to do with her
10 credibility. It's fair game.

11 MR. LOPEZ: Oh, okay. You are going to
12 testify --

13 MR. NORTH: She submitted a report that
14 addresses all of these filters, and she generically
15 lumps them together, so all are fair game.

16 MR. LOPEZ: I mean, you can use your
17 time as you wish, but...

18 THE WITNESS: Well, fine. If we go to
19 page 141, I'm discussing what I know about the
20 MERIDIAN -- 142. I haven't done a lot of research in
21 the MERIDIAN, and I basically looked at what the
22 company was saying that the MERIDIAN was going to
23 address in terms of a secure, safe filter. It's using
24 the same different -- the same use of elastic cranial
25 hit hooks. I talk about the marketing of the MERIDIAN

1 too, but I am board certified in pathology.

2 Q And you are still licensed to practice
3 medicine?

4 A Yes, sir.

5 Q In Arizona and Virginia?

6 A Yes, sir.

7 Q You are not a radiologist, are you?

8 A Correct.

9 Q And not an interventional radiologist?

10 A Correct.

11 Q Have you ever implanted an inferior vena cava
12 filter?

13 A No, sir.

14 Q In your medical practice, did you ever have
15 any dealings with a inferior vena cava filter?

16 A Not that I recall.

17 Q And my understanding is that you have not
18 treated a living patient since the 1980s; is that
19 correct?

20 A Correct. And the FDA -- and that the FDA
21 don't treat any living patients, that's correct.

22 Q And you were at the FDA for approximately
23 three or four years?

24 A I was from 1991 through 1995. Four years with
25 the Public Health Service, yes, sir.

1 Q And you began your consulting company in 1997?

2 A No, 1995 --

3 Q And --

4 A -- August.

5 Q -- ever since you left the FDA, you have
6 been -- your occupation has been a consultant?

7 A Yes, sir.

8 Q Are you still the only employee of your
9 company?

10 A My -- well, my husband has been my employee in
11 terms of doing all the billing and finances and
12 everything that I don't do.

13 Q You do not have training in engineering, are
14 you -- do you?

15 A Well, I have training from the FDA in
16 engineering because I would have to work with engineers
17 and read engineering drawings, and so I have on-the-job
18 training from engineering, so in terms of medical
19 device engineering.

20 Q But you've never studied engineering in an
21 academic setting, have you?

22 A I took a course in undergraduate school in
23 engineering, but I'm not an engineer.

24 Q And you are not a metallurgist?

25 A No, sir.

1 this year. And so I'm trying to cut back, and so
2 that's why I'm just not having as much time to consult
3 for medical device companies.

4 And also there are consultants, and --
5 but I have been a member of Regulatory Affairs
6 Professional, and I've given -- I've lectured for their
7 medical device courses online. I believe the course is
8 still online.

9 I've been primarily a talking head for
10 the Arizona Medical Association when they need someone
11 to talk about the FDA for various issues. I've talked
12 at the Biomedical -- Arizona Biomedical. So I've
13 mainly been a resource as opposed to a consultant in
14 the last couple of years.

15 Q How many active litigation cases do you have
16 right now?

17 A Actually right now, I'm down to maybe about
18 five.

19 Q Are all of those litigation cases on behalf of
20 plaintiffs?

21 A Yes.

22 Q Have you ever had a litigation case where you
23 were retained by the attorneys who represented a
24 medical device manufacturer?

25 A Yes.

1 Q On how many occasions over the years?

2 A Well, of the ones that have gone to
3 deposition, there's one, Clinical Diagnostics (sic).
4 It's on my list, and it's a fetal pressure monitor, and
5 so I gave a deposition testimony on that. I have
6 agreed to take cases, but oftentimes they don't go
7 beyond me having to -- I don't have to give testimony.

8 So I have nothing against taking a
9 defense case, and so -- and I've worked also for -- and
10 that was a medical device company.

11 Q On the list of testimony that we have, which I
12 believe was Exhibit 8 right here --

13 A Yes, sir.

14 Q -- you mentioned a deposition. Is there a
15 deposition listed where you were retained on behalf of
16 the medical device company?

17 A Yes, sir.

18 Q And how many depositions are -- or trial
19 testimonies are listed there where you were retained on
20 behalf of the device company?

21 A That would be the only one where I gave a
22 deposition.

23 Q What about for pharmaceutical companies in
24 there?

25 A No. And I've taken cases. I've also turned

1 Q On how many occasions have you met with
2 somebody from the Lopez McHugh firm --

3 A Only --

4 Q -- regarding this litigation?

5 A Only today.

6 Q All of your other communications during this
7 project have been by phone or e-mail?

8 A By phone.

9 Q Who have you dealt with primarily, Mr. Brenes
10 or Mr. Lopez?

11 A Both.

12 Q Did you write your report yourself?

13 A Yes, sir. All the typos are mine.

14 Q Have you ever published anything regarding
15 inferior vena cava filters?

16 A No, sir.

17 Q It sounds to me like it's fair to say -- or
18 I'm asking you, is it fair to say that you've had no
19 professional involvement with inferior vena cava
20 filters until your retention in this litigation?

21 MR. LOPEZ: Objection as to form.

22 THE WITNESS: I'm trying to -- I don't
23 recall if -- when I was with the FDA, we actually did
24 have some issues with inferior vena cava filters
25 because they were like Class III devices, and FDA was

1 kind of concerned what they were going to do with them
2 because they came out with the guidance in 1999.

3 So there were discussions, and I believe
4 there were some recalls and safety issues with them.
5 So I wouldn't say that professionally I've never had
6 anything to do with them, but I don't recall that they
7 were my responsibility. I was used as a chief medical
8 officer, and I would be involved in issues. And also
9 I've been involved in post-market issues.

10 So I know that I was introduced to the
11 inferior vena cava when I was at the FDA, so I don't
12 recall what capacity. I believe it was in post-market
13 safety issues.

14 Q BY MR. NORTH: As you sit here today, do you
15 have any specific recollection of what exactly you --
16 contact, if any, you had at the FDA with inferior vena
17 cava filters?

18 A No, sir.

19 Q And you never reviewed any 510(k) or premarket
20 applications regarding inferior vena cava filters, did
21 you?

22 A I wasn't the reviewer; I was the clinical
23 officer. I wouldn't have been the one reviewing these
24 applications. I would be called in as a consult, as a
25 medical officer. There's only ten medical officers in

1 was to be able to look at manufacturing and then to
2 come up with the health risk assessment as to the
3 potential effect on a patient and what needed to be
4 done in order to protect patients. So yes, I did do
5 that. I did that from '91 through '93.

6 Q I understand the good manufacturing practices,
7 regulations and quality assurance issues that those
8 pose, but do you have any experience in the engineering
9 aspects of manufacturing?

10 A Sometimes I did, yes. It was -- that's why I
11 had to be trained by the engineers. I had to be
12 trained how to produce things online, what the
13 verification process was, software, validation. So
14 yes, I had to do that, and so that was part of my
15 training.

16 Q My understanding is that you do have
17 experience in designing a medical device, and
18 particularly, a brain shunt and drug delivery device
19 for newborn infants. Is that correct?

20 A Well, those are two different devices.

21 Q Okay.

22 A One -- one would be the brain shunt which
23 would be the one from Stanford. They were looking at
24 Alzheimer's disease, and they needed to figure out how
25 to make a shunt that you can use in elderly people, so

1 I was the one that helped design the shunt and find the
2 material.

3 The surfactant was the drug delivery for
4 the newborn infants, and I had to help -- the company
5 wanted to have a device for delivery that would meet
6 CDRH standards, as well as CDR standards for drug and
7 device. So I had to help them with the design of that
8 product.

9 Q Are those the only two medical devices that
10 you've been personally involved in designing?

11 A From the ground up, from pencil to paper to
12 materials and to testing, and by a compatibility.
13 Yeah, those are the two that I designed from the
14 get-go.

15 Q And when were those projects? When did they
16 occur?

17 A They were back in the '90s. I'm not sure when
18 it was.

19 Q You've never served on the board of directors
20 of a medical device company, have you?

21 A No, sir.

22 Q And you have never run or operated a public
23 company, have you?

24 A That's correct.

25 Q And you've never worked in the regulatory

1 affairs of any drug or medical device manufacturer?

2 **A That's right. I've worked with -- as a**
3 **consultant.**

4 **Q And you've -- this I think is clear from your**
5 **previous testimony, that you've never designed an**
6 **inferior vena cava filter, have you?**

7 **A That's correct.**

8 **Q And you've never tested one?**

9 **A That's correct.**

10 **Q Have you ever been involved in the testing of**
11 **any medical devices, outside of possibly something with**
12 **the two you helped to design?**

13 **A Well, no. In terms of the consulting, some of**
14 **the issues would be testing of medical devices and how**
15 **to get clearance or how to address the safety issues.**
16 **So there were companies that I would look at their**
17 **testing. There are companies that I would come in and**
18 **look at their adverse event reports of complaints and**
19 **tell them what kind of testing to do. Those I can't**
20 **disclose because those were under confidential, but**
21 **some companies have me come in the back door and find**
22 **out what their problems are.**

23 **Q Well, I understand you may have looked at**
24 **testing before, but you have not actually conducted**
25 **tests on medical devices, have you?**

1 Q Do you maintain files on specific medical
2 device manufacturers?

3 A At one time I did. Now I don't.

4 Q You have testified in litigation involving
5 Bard before, haven't you?

6 A I believe so, yes, sir.

7 Q And that would have dealt with the hernia
8 patch litigation?

9 A Oh, yeah, the Davol, yes, sir, the Kugel Mesh.

10 Q Can you recall any other products, medical
11 devices involving Bard that you've testified
12 concerning?

13 A Not offhand. I don't have a file on Bard as
14 to what their history is. I did when I first started,
15 but I don't do that anymore. I don't do that anymore.

16 Q When did you stop doing that?

17 A I would have stopped probably in the beginning
18 of 2000. It's just -- I just -- I tend to now file
19 them by attorneys or issues.

20 Q Do you keep files based on the type of
21 products?

22 A It depends. Like, for example, pain pumps, I
23 was involved in a lot of pain pumps; different
24 manufacturers, same issues. So there is a file called
25 pain pumps, and there is all the different cases, all

1 the FDA for their files concerning Bard filters, did
2 you?

3 A No, sir.

4 Q Describe for me your methodology in reviewing
5 a product like this and preparing a report like this.

6 A It's the same methodology I used at the FDA.
7 I would go and I would look at -- basically do a glance
8 at what's on the FDA's Web site, what got cleared, what
9 the predicates are. You know, what -- how did this
10 product evolve in terms of other devices that were
11 similar.

12 So first I establish, how did this
13 product get on the market? And then I would look at
14 medical literature. I would look at discovery
15 documents that are provided, but first I have to figure
16 out in my own head how it got to be on the market, and
17 then I would look at the types of reports that are
18 being given, not just for this device, but for similar
19 devices as to what -- what are physicians writing about
20 it, what's -- so -- and that was how I always began at
21 the FDA. How did it get on the market? What are
22 people writing about it? What are the types of
23 reports?

24 I may look at the MDR database. I
25 didn't in this particular case because there are

1 documents that actually deal with the MDR database that
2 the company had.

3 Then I would focus more on the types of
4 complaints and looking at the manufacturing documents,
5 what I have from discovery, and then trying to put it
6 in context of how -- how it's -- you know, what types
7 of reports are being expressed in terms of the patients
8 that are the plaintiffs.

9 I oftentimes will ask, well, what kind
10 of plaintiffs are we seeing? What kind of reports are
11 we seeing? And so it's the same process I've done
12 since -- if you looked at a report I did back at the
13 FDA, it would almost be the same thing. How did this
14 come about? What's the science? And then what are
15 the -- what are the types of reports that are being
16 expressed? And then in this particular case, I would
17 focus specifically on C.R. Bard.

18 Q You mentioned the MAUDE database. You
19 reviewed documents regarding the data in the MAUDE
20 database with regard to Bard filters?

21 A In this particular case, the discovery
22 actually had MAUDE databases that had been reviewed by
23 the company. I didn't go back and do my own search of
24 the MAUDE. I could. But in this particular case, I
25 didn't need to expend that amount of time looking at

1 to tell you why?

2 MR. NORTH: You are going beyond the
3 Arizona rules. Let -- that's all --

4 MR. LOPEZ: I just asked you a question.
5 Do you want me --

6 MR. NORTH: No, I don't.

7 MR. LOPEZ: -- to tell you why? Okay.

8 THE WITNESS: I would discuss marketing
9 and what information is provided. But now what an
10 individual physician thought, he's going to have to
11 testify or she is going to have to testify for
12 themselves. I would be talking about in terms of the
13 regulatory, my role at the FDA as to adequate warnings,
14 instructions for use, off-labeled use. So those are
15 regulatory issues. But what one specific physician
16 thought, he's going to have to discuss that. I
17 can't -- I don't know the mind of a particular surgeon
18 or an implanter.

19 Q BY MR. NORTH: And your report in a number of
20 places talks about various marketing efforts on the
21 part of Bard, correct?

22 A Correct. And this is in the context of what I
23 would have done at the FDA. I would have been asked,
24 is this misleading? Is this false? You know, so it's
25 a regulatory context of a post-market sales of products

1 and what a company can say and do in terms of their
2 marketing. That's not in the brain of the one
3 particular surgeon. He will have to answer whether --
4 you know, whether he agrees with me or not, she -- he
5 or she.

6 Q You state an opinion in your report that the
7 Recovery filter was not substantially equivalent to the
8 Simon Nitinol Filter?

9 A Correct.

10 Q And why is it that you believe that?

11 A Based on the data that I've reviewed and the
12 testing, the performance of it, the internal company
13 documents, and based on the history of a permanent
14 filter, the types of complications you see for the
15 Simon Nitinol, it wasn't substantially equivalent for
16 that. And a lot of that would be even in the document
17 that I gave you today that I reviewed in terms of the
18 testing between the Simon Nitinol and the -- and the
19 Recovery filter; you will see my handwritten notes
20 about the different performances of the Simon Nitinol
21 back in '98 and '99. So it goes -- it stems back to
22 their own testing. So --

23 Q What data --

24 A -- it's based on facts.

25 Q What data did you have about the complication

1 testing before they had the final device. So it
2 actually had been on the prototype, not on the
3 manufactured device. So I haven't seen any fatigue
4 testing on the final device.

5 Q Did you review any of the laboratory notebooks
6 regarding the test?

7 A I think I have. That's why I brought
8 documents that I have reviewed in terms of some of the
9 testing documents. The notebooks, per se, I don't know
10 if I've reviewed the notebooks because that's
11 oftentimes what a scientist will keep track of. But
12 some of the data from those notebooks are in their
13 final reports.

14 Q Have you ever conducted any studies about the
15 nature of the stresses that occur within the inferior
16 vena cava filter?

17 A No.

18 Q Have you formed an opinion as to anything
19 specific about the design of the Recovery filter that
20 you believe was defective?

21 A If I was consulting for a manufacturer wanting
22 to make an IVC filter, one of the things that I would
23 take into consideration or would want them to test
24 would be the vena cava -- the environment of the vena
25 cava and the changes in the stress.

1 selling it anymore because it's got all these risks and
2 we are just monitoring safety issues. That's not what
3 they told the FDA. They didn't tell the FDA anywhere
4 that they stopped manufacturing it because of issues
5 when they are getting the G2 approved -- cleared.

6 So that's the type of safety information
7 that ODE is not -- is not -- they don't think of that
8 types of information. The company has to tell them
9 that there are relevant safety issues going on with
10 this Recovery that we've chosen as our predicate, and
11 we are not going to market it anymore. You can't do
12 that.

13 That's why I said they could have chosen
14 any other predicate. They could have chosen the SNT
15 and made sure that it actually performed like the
16 SNT -- the SNF, but they didn't. They chose the
17 Recovery, which is a product they knew they were going
18 to internally stop manufacturing, and just let it sit
19 on the market that had problems, and you can't do that,
20 and the process doesn't allow that.

21 So that's what -- the company was the
22 one who actually misbranded the product and did not
23 comply with regulations in terms of providing FDA
24 relevant safety information so the FDA could ask
25 additional testing or information about the product.

1 Recovery. Yeah, so I was wrong. It's not the G2; it
2 was the 2004 was the Recovery. I thought there was
3 another letter.

4 And so, again, if you go to page 127,
5 Ms. Allen talking to FDA talking about sending out the
6 Dear Doctor letter in 2005. I guess it begins on page
7 123, paragraph 397. That would be the first one that
8 had been written as needed. And then there is another
9 discussion about a letter that's going to be sent out
10 on -- by -- you get to paragraph 413, letter of
11 May 11th, 2005, and again it was a Recovery filter, so
12 they were both Recovery filter.

13 Q You have discussed at great length today your
14 opinions that Bard did not provide sufficient
15 information to the FDA in its 510(k) submission for the
16 Recovery filter, correct?

17 A In the context of safety for patients, so they
18 provided information, but it wasn't relevant safety
19 information as to the performance of the Recovery
20 filter.

21 Q Did Bard provide any information or data in
22 its 510(k) submissions that was false?

23 A Well, it said the migration resistance was
24 going to be substantial equivalent to the Simon Nitinol
25 Filter. That's false. And that it was substantially

1 equivalent to the Simon Nitinol Filter, that's false.
2 So it claimed that it was substantially equivalent to
3 the predicate, that it wasn't, and it didn't perform
4 that way as a permanent filter.

5 And the company was the one who chose it
6 to make it a permanent filter. The FDA actually would
7 ask for them to limit the length of time it was
8 implanted. Twice they asked them to do that, and both
9 times the company said it was a permanent filter and
10 they didn't want to limit the doctor as to when to
11 remove the filter.

12 They did that with the retrieval option
13 for the Recovery, and they did it again for the
14 retrieval option for the G2. FDA tried to limit --
15 requested that the company limit the data for how long
16 it could be implanted, and the company opted both times
17 to say, no, it's a permanent filter.

18 Q You are saying that the FDA attempted to get
19 Bard to limit the amount of time that the filter could
20 be implanted so that therefore it would not be used as
21 a permanent filter?

22 MR. LOPEZ: Objection as to form.

23 THE WITNESS: What the FDA did -- and
24 they did -- in the Recovery label, they do have the
25 Asch data and about -- the information about how long

1 Recovery -- the Recovery filter is not substantially
2 equivalent to the Simon Nitinol Filter as a permanent
3 filter. It does say -- it indicates it's a permanent
4 filter and it has not been tested, it had not been
5 designed, it had been not developed to be a permanent
6 filter. So right there it begins by saying it is a
7 permanent filter. That's wrong.

8 Q I'm not meaning to interrupt. We will get
9 back to doing the other things, but while you are on
10 that point, can I ask you some follow-up, and then I
11 will ask you for the other points you think.

12 If the company knows or believes that
13 the device it's selling is not substantially equivalent
14 to the identified predicate, isn't the answer to that
15 to quit selling the product and not to put a warning in
16 the IFU?

17 A I agree with you. I said it shouldn't have
18 been sold.

19 Q Right.

20 A You are asking me about the IFU. It shouldn't
21 have even been on the market. So now if you are going
22 to continue to market an adulterated and misbranded
23 device and you want me to help you write a label, you
24 would say you are not a permanent filter; that you've
25 never been tested, designed or looked at as a permanent

1 device. They put a label that was like that they were
2 substantially equivalent. They put a label that got
3 them cleared, but it was not an appropriate label. It
4 was basically a zebra that they are saying is a horse,
5 and FDA needed to approve it, clear it as a horse.
6 It's a zebra.

7 And so the company shouldn't have
8 marketed it in the first place. Once they knew that
9 there was a problem, they should have pulled it. They
10 should have found a product that actually worked or
11 sold their own Simon Nitinol Filter. Their own
12 salespeople don't know about the Simon Nitinol Filter
13 to sell it as a suitable alternative for a permanent
14 filter.

15 Q Your opinion report at some point says that we
16 failed -- Bard failed to warn physicians about
17 deployment issues. What do you mean by that?

18 A Well, those are in terms of their internal
19 documents, that they were deployment issues in terms of
20 the femoral and the jugular kits. That's basically
21 from Bard's tracking deployment issues, and so that's
22 another issue about the difficulty of putting the
23 device in.

24 One of the issues is that if you have a
25 deployment problem, you can actually have it embolize

1 any evidence that Bard was affirmatively marketing the
2 product for that use?

3 A It's awareness. It's awareness alone. That
4 you are aware of it, you have a duty. You have a duty
5 to either get that clearance so that your product is
6 being used legally, or you have a requirement under
7 801.4 to update your warnings to warn against it. So
8 it's awareness alone. It doesn't -- and I don't even
9 have to show them where the document is saying
10 off-labeled use. It triggers the responsibility of a
11 manufacturer selling a product in the United States.
12 You take an action, and they didn't take the action.

13 Now, in terms of off-labeled use, we
14 have Dr. Asch with his live case studies presentations,
15 two physicians in 2002 before the device, the Recovery
16 is cleared for retrievable use, and he's showing it in
17 his Canadian patients to American physicians. It's not
18 even cleared for permanent filter use, and the company,
19 Bard, is having these live case presentations.

20 You can't do that. That's off-labeled
21 use right there. The Recovery wasn't even cleared for
22 any indication, and then he's showing how to retrieve
23 it. It wasn't -- it wasn't cleared until a year later
24 for that indication.

25 So that's an example of off-labeled use

1 right there, that Dr. Asch, and then his article is
2 published in 2002 about the time that the Recovery was
3 cleared. There's nothing in there that's saying this
4 is investigational use. You can't use it for
5 retrieval. You can't do that. That's again promoting
6 off-labeled use for the Recovery for retrieval. You
7 couldn't do that. So that's another example.

8 So all these things, as a responsible
9 manufacturer, Bard can't do. He cannot promote
10 off-labeled use for a product that wasn't cleared. He
11 can't promote off-labeled use for a product that's not
12 cleared for retrieval.

13 And then we have the G2. The G2 was not
14 cleared for Recovery until 2008, but I don't see Bard
15 saying, oh, we don't market a product now that we've
16 stopped in 2005 for Recovery, and the Recovery is
17 not -- G2 is not cleared for Recovery until 2008. It
18 seems like they are still marketing retrievable filter
19 in there, and they are not necessarily producing one
20 that's safe and effective. So Bard off-labeled use all
21 over the place, and then they are following off-labeled
22 use.

23 So I don't know what -- so, yeah, I
24 don't have a document where it says here bariatric, but
25 I know they are going to bariatric conferences. They